

DETAILED ACTION

Status of Claims

The previous Final Action on the Merits dated 11/14/2007 is hereby vacated. The following rejections and/or objections are now newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11 and 15 are pending, with new claim 15 added on 10/24/2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9-11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al. (Applicants' IDS dated 7/10/2006) in view of STOWE et al (Women at risk for postpartum-onset major depression. American Journal of Obstetrics and Gynecology, Vol. 173, Issue 2, August 1995, Pages 639-645).

SCHATZBERG et al teaches the use of treating psychosis associated with major depression in a patient in need thereof by administering a glucocorticoid receptor antagonists (see claim 1), but does not specifically state postpartum depression as the population to be treated. Additionally, SCHATZBERG et al defines "glucocorticoid receptor antagonist" (column 4 line 64-column 5 line 4) with the same definition as the instantly defined "specific glucocorticoid receptor antagonist" (page 6 lines 22-29).

STOWE et al teaches postpartum-onset major depression as a form of major depression (see page 640):

In contrast, controlled studies with standard psychiatric rating scales⁸⁰ and structured interviews²¹ have not demonstrated significant differences in individual symptom items between primary depression and PPD.

Postpartum is by its nature defined as a condition which typically shows symptoms within the first 4 weeks after child birth (page 639, right column lines 3-5). While STOWE et al acknowledges a personal psychiatric history increases the risk for

post partum depression, it can be inferred that a personal psychiatric history is not required for post partum depression (page 640, Psychiatric history section).

One of ordinary skill in the art would understand that post partum depression (PPD) would fit within the category of major depression psychosis and would therefore treat the patient population with the glucocorticoid receptor antagonists of SCHATZBERG, et al.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al, in view of STOWE et al, in view of BRADLEY et al, (PTO-892 dated 9/20/2007, J. Med. Chem. 45, 2417-2424 (2002)).

SCHATZBERG et al and STOWE et al do not teach when the specific glucocorticoid receptor antagonists listed in claim 7.

BRADLEY et al, J. Med. Chem. 45, 2417-2424 (2002) teach GR antagonist compounds (see title, abstract, and pg 2417 first full paragraph) 4 α (S)-Benzyl-2(R)-prop-1-ynyl- 1,2,3,4,4 α ,9,10,10 α (R)-octahydro-phenanthrene-2,7-diol diol (pg 2421 3rd full paragraph) and 4 α (S)-Benzyl-2(R)- chloroethynyl-1,2,3,4,4 α ,9,10,10 α (R)-octahydro-phenanthrene-2,7-diol (pg 2421 2nd full paragraph).

Someone of ordinary skill in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, and which would have an obvious reasonable expectation of success.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al, in view of STOWE et al, in view of GEBHARD (PTO-892 dated 9/20/2007, US 6,011,025).

SCHATZBERG et al and STOWE et al do not teach when the specific glucocorticoid receptor antagonists listed in claim 8.

GEBHARD claims the glucocorticoid receptor antagonist (11 β ,17 β)- 11-(1,3-benzodioxol-5-yl)-17-hydroxy-17-(1 -propynyl)estra-4,9-dien-3-one (see abstract and claim 6).

Therefore, someone of ordinary skill in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, , and would have a reasonable expectation of success.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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12 December 2007

BP

/Ardin H Marschel/

Supervisory Patent Examiner, Art Unit 1614